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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,481	07/11/2003	Tony Hollingsworth	NE-0004	8213

7590

09/06/2006

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EXAMINER
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JOYCE, CATHERINE

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/618,481	HOLLINGSWORTH ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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1. The Amendment filed June 12, 2006 in response to the Office Action of March 17, 2006 is acknowledged and has been entered. Claims 1-3 are pending, claim 2 is withdrawn from consideration as being drawn to a non-elected invention, and claims 1 and 3 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. The following rejections are being maintained:

***Claim Rejections - 35 USC 102***

4. Claims 1 and 3 remain rejected under 35 USC 10(b) as being anticipated by WO 02/058450, for the reasons set forth previously in the Paper mailed March 17, 2006, Section 6, pages 3-4.

Applicant argues (i) that the cited reference does not teach or suggest "an isolated MUC1 cytoplasmic tail peptide" of the specified sequences of SEQ ID NO:3-49 and (ii) that the cited reference teaches peptides that inhibit the physical interaction between MUC1 and tumor progressors whereas Applicants disclose MUC1 peptides for eliciting an immune response to MUC1-expressing tumor cells.

Applicant's arguments have been considered but have not been found to be persuasive. With regard to the first argument, claim 1, as currently constituted, recites "[a] composition for preventing or treating cancer in a subject comprising at least a portion of an isolated MUC1 cytoplasmic tail peptide of SEQ ID NO:1, wherein said portion is selected from the group consisting of SEQ ID NOs: 3-49". Thus, claim 1, as currently constituted, is not limited to peptides of the indicated SEQ ID NOs but reads on polypeptides comprising the indicated SEQ ID NOs. As set forth in the previous Office Action, WO 02/058450 describes a composition comprising a polypeptide having the amino acid sequence of SEQ ID NO:1 of the instant application, a composition comprising a polypeptide having the amino acid sequence of amino acid residues 1 to

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42 of SEQ ID NO:1 of the instant application, and a composition comprising a polypeptide having the amino acid sequence of amino acid residues 22 to 72 of SEQ ID NO:1 of the instant application. Thus, the polypeptide compositions of WO 02/058450 would comprise a cytoplasmic tail peptide of SEQ ID NO:1 and thus would also comprise "at least a portion of an isolated MUC1 cytoplasmic tail peptide of SEQ ID NO:1" wherein the portion is any of the SEQ ID NOs specified in claim 1, or certain of the specified SEQ ID NOs. For example, the peptide of WO 02/058450 that comprises amino residues 1 to 42 of SEQ ID NO:1 would encompass the instantly claimed SEQ ID NO:11 that is amino acids 4-11. With regard to the second argument, as set forth in the previous Office Action, recitation of "for preventing or treating cancer" (claim 1) and "comprises a vaccine" (claim 3) are merely suggestive of an intended use and are not given weight for purposes of comparing the claims with the prior art. Thus, the claims read on the active ingredient *per se*, which is the claimed polypeptides.

5. Claims 1 and 3 remain rejected under 35 USC 10(b) as being anticipated by US Patent 6,548,643, for the reasons set forth previously in the Paper mailed March 17, 2006, Section 7, pages 4-5.

Applicant argues that the cited reference does not teach or suggest "an isolated MUC1 cytoplasmic tail peptide" of the specified sequences of SEQ ID NO:3-49.

Applicant's arguments have been considered but have not been found to be persuasive. With regard to the first argument, claim 1, as currently constituted, recites "[a] composition for preventing or treating cancer in a subject comprising at least a portion of an isolated MUC1 cytoplasmic tail peptide of SEQ ID NO:1, wherein said portion is selected from the group consisting of SEQ ID NOs: 3-49". Thus, claim 1, as currently constituted, is not limited to peptides of the indicated SEQ ID NOs but reads on polypeptides comprising the indicated SEQ ID NOs. As set forth in the previous Office Action, US Patent 6,548,643 teaches conjugates between an antigen and a carbohydrate polymer, wherein the conjugates may be immunogenic vaccines, and that preferred peptides comprises amino acids 1-21 or 35-54 of the intracellular portion of

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MUC 1 (i.e. of SEQ ID NO:1 of the instant application). Thus, the polypeptide compositions of US Patent 6,548,643 would comprise "at least a portion of an isolated MUC1 cytoplasmic tail peptide of SEQ ID NO:1" wherein the portion is some of the specified portions. For example, the peptide of US Patent 6,548,643 that comprises amino residues 35 to 54 of SEQ ID NO:1 would encompass the instantly claimed SEQ ID NO:26 that is amino acids 40-49.

6. All other objections and rejections recited in the previous Office Action are hereby withdrawn.

7. No claims allowed.

8. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

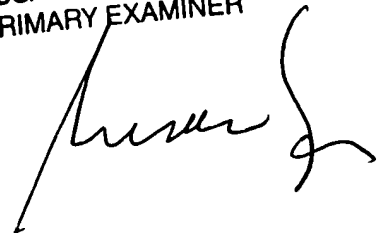
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine M. Joyce  
Examiner  
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SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan Ungar', is written over the printed name and title.